

**REMARKS**

Applicants respectfully request reconsideration of the present case in view of the above amendments and the following remarks.

Claims 1-17, 21-44, 46, 48, 50 and 52-64 are currently pending. Claims 25 and 26 have been amended. No new matter has been inserted. Support for the amendment of claims 25 and 26 can be found throughout the specification.

**35 U.S.C. § 112**

Claims 1-17, 21-44, 46, 48, 50 and 52-64 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully traverse this rejection.

The Examiner stated that it was not clear from claims 1 and 31-34 if the chemical moieties of formulas (II), (III), (IV) and (V) were deleted. In response, Applicants point out that lines were drawn through these moieties in the last response and herein confirm that these formulas were deleted from claims 1 and 31-34. Applicants respectfully request that this rejection be withdrawn.

The Examiner stated that “it is not clear from claim 3 what is the second glycoalkaloid.” In response, Applicants point out that claim 3 recites “A composition according to claim 1 wherein the glycoalkaloids are solasodine glycosides.” Accordingly claim 3 does not make reference to a “second glycoalkaloid” as suggested by the Examiner. Applicants respectfully request that this rejection be withdrawn.

The Examiner alleged that there is no antecedent basis for the term “glycoalkaloids” in claims 25-26. While not conceding the correctness of the Examiner’s position, in the interest of advancing prosecution, Applicants have amended claims 25 and 26 to obviate this rejection. Applicants respectfully request that this rejection be withdrawn.

**35 U.S.C. § 102(b)**

Claims 1-17, 21-44, 46, 48, 50 and 52-64 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over

Australian Patent No. AU-B-57853/80, International Patent No. 91/10743, or International Patent No. WO 00/61153. Applicants respectfully traverse this rejection.

The Examiner responded to arguments made by Applicants stating that “the term ‘isolated’ is not limited to pure compounds but encompasses a compound with additional impurities or in the form of an extract.” Applicants disagree with the Examiner over the meaning of the term ‘isolated’ as used in this case. According to MPEP § 2111.01, “Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim.” *See Toro Co. v. White Cons. Indus. Inc.*, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). In the present case, Applicants have provided an explicit definition for the term “isolated.” Specifically, Applicants draw the attention of the Examiner to the specification at page 7, lines 11-17:

“For the purposes of the present invention the term “isolated” means essentially free of (i) mono and diglycosides and, preferably, essentially free of (ii) free sugars such as mono, di, tri, oligo or polysaccharides and (iii) aglycone.”

Therefore, Applicants assert that this definition controls interpretation of the term “isolated” as it is used in the pending claims.

By way of example, claim 1 requires that “when the glycoalkaloids are solamargine and solasonine and they are present in a 1:1 ratio the solamargine and solasonine are isolated.” Therefore, Applicants submit that Australian Patent No. AU-B-57853/80, International Patent No. 91/10743, and International Patent No. WO 00/61153, either individually or in combination, fail to teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64.

Specifically, AU 57853/80 (Cham et al.) describes the preparation of an extract from *Solanum sodomium* (referred to BEC-001), a cream formulation containing the extract, the use of BEC-001 to treat sarcoma in mice and some anecdotal evidence of the use of BEC-001 to treat skin cancer. Figure 1 of AU 57853/80 clearly shows that BEC-001 is a relatively crude extract comprising 4 main components: (i) mono and diglycoside forms of solasodine; (ii) solasodine (an aglucone); (iii) solamargine; and (iv) solasonine.

In sharp contrast, the claims of the present invention are directed to a composition comprising a particular ratio of two triglycoside glycoalkaloids, on the proviso that when the glycoalkaloids are solamargine and solasonine they are isolated (*i.e.* essentially free of mono and diglycosides). There is no data in AU 57853/80 that would lead a skilled person to combine the glycoalkaloids in the manner described and claimed in the present application. Accordingly, AU 57853/80 does not teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64.

WO 00/61153 (Cham) fails to anticipate the claims of the invention and/or cure the deficiencies of AU 57853/80. WO 00/61153 (Cham) discloses that free sugars (principally rhamnose) in BEC that are formed from the degradation of glycoalkaloids therein can inhibit the activity of BEC. The examples of WO 00/61153 describe the preparation of BEC that is then “washed” using solvent extractions to improve its activity. Importantly, the washed BEC compositions in WO 00/61153 include the mono and diglycoside forms of solamargine and solasonine (see examples 1 and 5 therein).

Again, in sharp contrast, the claims of the present invention are directed to a composition comprising a particular ratio of two triglycoside glycoalkaloids, on the proviso that when the glycoalkaloids are solamargine and solasonine they are isolated (*i.e.* essentially free of mono and diglycosides). Again, there is no data in WO 00/61153 that would lead a skilled person to combine the glycoalkaloids in the manner described and claimed in the present application. Accordingly, the combination of AU 57853/80 and WO 00/61153 does not teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64.

WO 91/10743 fails to anticipate the claims of the invention and/or cure the deficiencies of AU 57853/80 and WO 00/61153 (Cham). WO 91/10743 describes the results of a number of tests on cell lines and sperm exposed to (i) solamargine alone, (ii) solasonine alone, (iii) a mixture of mono and diglycosides alone or (iv) BEC (a mixture of solasonine, solamargine, free sugars and mono and diglycosides) see Tables 1-7 and Figures 1-10 of WO 91/10743.

As discussed above, the claims of the present invention are directed to a composition comprising a particular ratio of two triglycoside glycoalkaloids, on the proviso that when the glycoalkaloids are solamargine and solasonine they are isolated (*i.e.* essentially free of mono and diglycosides). There is no data in WO 91/10743 that would lead a skilled person to combine the glycoalkaloids in the manner described and claimed in the present application. Accordingly, WO 91/10743 does not teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64.

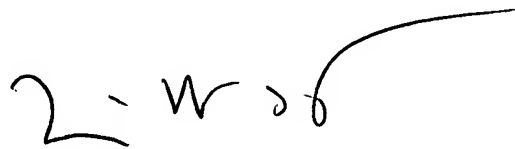
For at least these reasons, Applicants submit that Australian Patent No. AU-B-57853/80, International Patent No. 91/10743, and International Patent No. WO 00/61153, either individually or in combination, fail to teach or suggest the invention of claims 1-17, 21-44, 46, 48, 50, and 52-64. Applicants respectfully request that this rejection be withdrawn.

**Summary**

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

23 February 2005  
Date

  
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